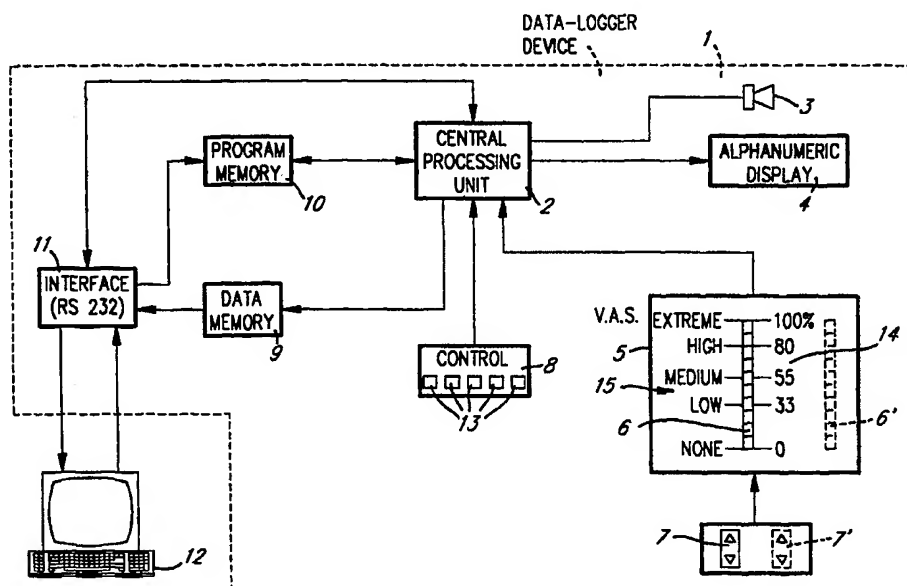




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61B 5/00</b>	<b>A1</b>	(11) International Publication Number: <b>WO 99/05960</b> (43) International Publication Date: 11 February 1999 (11.02.99)
<p>(21) International Application Number: PCT/CA97/00544</p> <p>(22) International Filing Date: 30 July 1997 (30.07.97)</p> <p>(71) Applicant: UNIVERSITE DE MONTREAL [CA/CA]; 2900 Édouard-Montpetit, Montreal, Quebec H3T 1J4 (CA).</p> <p>(72) Inventors: DAIGLE, Serge; 301 Lauzon, Rouyn Noranda, Quebec J9X 3T8 (CA). MARCHAND, Serge; 11 MacDonald, Rouyn Noranda, Quebec J9X 1A3 (CA). BUSHNELL, Catherine; 772 A Bloomfield, Outremont, Quebec H2V 3S3 (CA). LAVIGNE, Gilles; 319 Monmouth, Ville Mont-Royal, Quebec H2P 2B3 (CA). SAINT-JACQUES, Sylvain; 808 Rabelais, Deux-Montagnes, Quebec J7R 6S2 (CA).</p> <p>(74) Agents: DUBUC, Jean, H. et al.; Goudreau Gage Dubuc &amp; Martineau Walker, The Stock Exchange Tower, Suite 3400, 800 Place Victoria, P.O. Box 242, Montreal, Quebec H4Z 1E9 (CA).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b> With international search report.</p>

(54) Title: PORTABLE AND PROGRAMMABLE INTERACTIVE VISUAL ANALOGUE SCALE DATA-LOGGER DEVICE



## (57) Abstract

A portable, interactive clinical data-logger device signals to a patient under investigation a succession of recording time periods spaced apart by predetermined time intervals. After a recording time period has been signalled, questions such as "What intensity of pain are you feeling?", "What degree of discomfort are you feeling?" or "How severe is a given symptom?" are displayed. The patient answers each question by means of a pushbutton-controlled bar graph associated to a pain intensity, discomfort degree and/or symptom severeness representative V.A.S. scale. The V.A.S. data are then stored and available for further processing into an outside computer.

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

5

PORTABLE AND PROGRAMMABLE INTERACTIVEVISUAL ANALOGUE SCALE DATA-LOGGER DEVICE

10

BACKGROUND OF THE INVENTION1. Field of the invention:

15

The present invention relates to a portable clinical data-logger device of the visual analogue scale (V.A.S.) type to be carried by the patient. This data-logger device is both interactive and programmable, and finds wide applicability in research and clinical practice.

20

2. Brief description of the prior art:

25

The company **Autenta AB**, Box 9028, S-750 09 Uppsala, Sweden is fabricating and commercializing a data-logger of the above type, under the name SYMTRACK®. The SYMTRACK® data-logger is portable and carried by the patient to record the intensity/severity of a given symptom in time.

30

5                   The SYMTRACK® data-logger emits a signal to remind the patient of each recording procedure. User selectable sample periods of 1, 5 or 10 minutes are available.

10                   At each recording, the patient indicates by means of a visual analogue scale (V.A.S.) the intensity/severity of the symptom. Corresponding symptom data are then recorded and available for analysis purposes.

15                   By concealing previous recordings from the patient, the SYMTRACK® data-logger prevents the patient to enter symptom data retrospectively. As retrospective symptom data are notoriously inaccurate, 20 the SYMTRACK® data-logger substantially improves the accuracy of the collected data.

                  The SYMTRACK® data-logger presents the following drawbacks:

- 25
- programming is limited (for example, a very limited number of user selectable sample periods are available);
- 30
- data relative to only one symptom can be recorded at a time.

5

OBJECTS OF THE INVENTION

10           An object of the present invention is  
therefore to provide a portable visual analogue scale  
data-logger device which is fully programmable.

15           Another object of the present invention is  
to provide a portable visual analogue scale data-  
logger device which is interactive to enable recording  
at the same time of different types of clinical data.

SUMMARY OF THE INVENTION

20

25           More specifically, in accordance with the  
present invention, there is provided a portable,  
interactive data-logger device for recording clinical  
data relative to a patient under investigation,  
comprising:

timer means for signalling to the patient  
a succession of recording time periods spaced apart by  
predetermined time intervals;

5 means for communicating a message to the patient after a recording time period has been signalled;

data-entering means for allowing the patient to enter clinical data relative to the patient and related to the message; and

10

memory means for receiving and storing the entered clinical data.

In accordance with preferred embodiments of the portable, interactive data-logger device of the invention:

15

- the message communicating means comprises a display unit for displaying a question to be answered by the patient;

20

- the portable, interactive data-logger device further comprises means for turning the data-logger device on, the message communicating means then comprising means for communicating a message to the patient following turning on of the data-logger device;

25

- the portable, interactive data-logger device further comprises means for preventing the patient to enter or alter any data entered during one

30

5        recording time period after this recording time period  
has elapsed;

                         - the message asks to the patient what  
intensity of pain he is feeling, what degree of  
10       discomfort he is feeling, and/or how severe is a given  
symptom, the data-entering means comprises means for  
allowing the patient to enter the intensity of pain he  
is feeling, the degree of discomfort he is feeling  
and/or the severeness of the given symptom;

15

                         - the data-entering means comprises a bar  
graph, scale means along the bar graph, and pushbutton  
means for controlling the bar graph;

20

                         - the time intervals between the  
successive recording time periods and the message to  
be communicated to the patient after a recording time  
period has been signalled are fully programmable; and

25

                         - the message communicating means  
comprises means for communicating to the patient a  
plurality of messages, and the data-entering means  
comprises means for allowing the patient to enter  
clinical data related to each message.

30

5                   The objects, advantages and other features  
of the present invention will become more apparent  
upon reading of the following non restrictive  
description of a preferred embodiment thereof, given  
by way of example only with reference to the  
10 accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

15

In the appended drawings:

Figure 1 is a schematic block diagram of  
the preferred embodiment of the portable and  
20 programmable interactive visual analogue scale  
(V.A.S.) data-logger device according to the  
invention, comprising a central processing unit, an  
electroacoustic transducer, an alphanumeric display,  
a V.A.S. including a bar graph controllable through an  
25 up/down pushbutton switch, a control keyboard, a data  
memory, a program memory and an RS 232 port interface;  
and

Figure 2 is a flow chart showing operation  
30 of the portable and programmable interactive visual



5        analogue scale (V.A.S.) data-logger device of Figure  
1.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

10

Referring to Figure 1 of the appended drawings, the portable and programmable interactive visual analogue scale (V.A.S.) data-logger device 1,  
15        hereinafter referred to as "data-logger device 1" comprises:

- a central processing unit 2;
- 20        - an electroacoustic transducer 3  
connected to the central processing unit 2;
- an alphanumeric display 4 connected to  
the central processing unit 2;
- 25        - a V.A.S. unit 5 connected to the central  
processing unit 2 and including a bar graph 6  
controllable through an up/down pushbutton switch 7;

5                   - a control keyboard 8 comprising a plurality of keys 13 and connected to the central processing unit 2;

                  - a data memory 9 connected to the central  
10               processing unit 2;

                  - a program memory 10 in bidirectional communication with the central processing unit 2; and

15               - an RS 232 port interface 11 connectable to an outside personal computer 12 to establish bidirectional communication between the personal computer 12 and the central processing unit 2, unidirectional communication from the personal  
20               computer 12 to the program memory 10 and unidirectional communication from the data memory 9 to the personal computer 12.

                  Reference will now be made to both Figures  
25               1 and 2 to describe operation of the data-logger device 1.

                  The data-logger device 1 is programmed (step 20 of Figure 2) for recording clinical data  
30               relative to a patient under investigation. Programming is carried out by means of the personal

5 computer 12 through the RS 232 port interface 11.  
More specifically, the personal computer 12  
communicates with the central processing unit 2 to  
store the new program in the memory 10.

10 In particular, successive recording time  
periods spaced apart by predetermined time intervals  
are programmed along with questions to be answered by  
the patient at each recording time period. Different  
questions may be asked to the patient at successive  
15 recording time periods, and the time intervals between  
the successive recording time periods is programmable  
at will.

Examples of questions that can be asked to  
20 the patient are the following:

- What intensity of pain are you  
feeling?;
- 25 - What degree of discomfort are you  
feeling?;
- How severe is (a given symptom) ?;
- 30 - etc.

5                   A timer is incorporated in the central  
processing unit 2 to allow this central processing  
unit 2 to signal to the patient each recording time  
period (step 21 of Figure 2). This is carried out by  
the central processing unit 2 by emitting a sound  
10 signal through the electroacoustic transducer 3.

                  In response to the sound signal emitted  
through the electroacoustic transducer 3, the patient  
should turn the data-logger device 1 on (step 22 of  
15 Figure 2) by depressing one of the keys 13 of the  
control keyboard 8.

                  Each recording time period has a given  
length. After a recording time period has been  
20 signalled, the central processing unit 2 counts time.  
After the recording time period has elapsed (step 23  
of Figure 2) the program returns to step 21 and the  
patient is no longer enabled to enter and/or alter any  
data related to this particular recording time period.  
25 A corresponding message is then displayed (step 24 of  
Figure 2) on the alphanumeric display 4. This  
prevents the patient to enter data retrospectively,  
retrospective data being as mentioned in the foregoing  
description notoriously inaccurate.

5                   As long as the recording time period has  
not elapsed (step 23 of Figure 2), the patient is  
enabled to enter data. It should be pointed out here  
that the length of the recording time periods is well  
sufficient to allow the patient to enter the clinical  
10 data related to the questions.

                  If the recording time period is not  
elapsed, the central processing unit 2 is responsive  
to turning on of the data-logger device 1 to display  
15 on the alphanumeric display 4 a message, in particular  
but not exclusively a question to be answered by the  
patient (step 25 of Figure 2).

                  For example, if the question is "What  
20 intensity of pain are you feeling?", the patient  
operates the up/down pushbutton switch 7 (step 26 of  
Figure 2) to control the bar graph 6 so as to indicate  
the intensity of pain he is feeling on the 0-100%  
scale 14 (Figure 1) appearing along that bar graph 6.  
25 To facilitate answering by the patient, indications  
such as NONE, LOW, MEDIUM, HIGH and EXTREME (see 15 in  
Figure 1) are distributed along the scale 14.

                  The patient then depress an "ENTER" key  
30 (step 27 of Figure 2) amongst the keys 13 of the  
keyboard 8 to command the central processing unit 2 to

5       store or record in the memory 9 the V.A.S. data  
indicative of the intensity of the pain the patient is  
feeling (step 28 of Figure 2).

10               If the patient has to answer another  
question (step 29 of Figure 2) in the same recording  
time period, the program of the central processing  
unit 2 returns to step 25 and steps 25-28 are repeated  
for the additional question.       Therefore, many  
questions may be asked to the patient during each  
15       recording time period.

              As another example, if the question is  
"What degree of discomfort are you feeling?", the  
patient operates the up/down pushbutton switch 7 to  
20       control the bar graph 6 so as to indicate the degree  
of discomfort he is feeling on the 0-100% scale 14  
(Figure 1) taking into consideration the indications  
15.

25               The questions "What intensity of pain are  
you feeling?" and "What degree of discomfort are you  
feeling?" can be combined and the V.A.S. unit provided  
with two bar graphs 6 and 6' respectively controlled  
through up/down pushbutton switches 7 and 7'. To  
30       answer, the patient operates the up/down pushbutton  
switches 7 and 7' to indicate the intensity of pain

5 through the bar graph 6 and the degree of discomfort  
he is feeling through the bar graph 6', that is on the  
0-100% scale 14 (Figure 1) taking into consideration  
the indications 15. Depression of the "ENTER" key of  
the keyboard 8 (step 27) will then cause recording of  
10 both V.A.S. data (step 28) related to the intensity of  
pain and degree of discomfort.

Another possible question is "How severe  
is (a given symptom) ? ". Again, to answer that  
15 question the patient operates the up/down pushbutton  
switch 7 to indicate, by means of the bar graph 6, how  
severe is the symptom of concern on the 0-100% scale  
14 (Figure 1) taking into consideration the  
indications 15.

20 Those skilled in the art will appreciate  
that a plurality of other messages such as questions  
can be contemplated to collect clinical data  
concerning a given patient and related to these  
25 messages. The present invention is in no way limited  
by the type of messages.

When no additional question is to be  
answered (step 29 of Figure 2), an "END" message is  
30 displayed on the alphanumeric display 4 (step 30 of

5       Figure 2). The patient then turns the data-logger device 1 off (step 31 of Figure 2).

10       The V.A.S. data collected in the memory 9 can be retrieved by the outside personal computer 12 through the RS 232 port interface 11 and through appropriate commands transmitted to the central processing unit 2. The collected data can then be processed as desired in the computer 12.

15       The dimensions of the portable data-logger device 1 are as reduced as possible to be easily carried by the examiner. Acceptable dimensions are those of an electronic calculator.

20       Although the present invention has been described hereinabove by way of a preferred embodiment thereof, this embodiment can be modified at will, within the scope of the appended claims, without departing from the spirit and nature of the subject  
25       invention.



WHAT IS CLAIMED IS:

1. A portable, interactive data-logger  
5 device for recording clinical data relative to a  
patient under investigation, comprising:

timer means for signalling to the patient  
a succession of recording time periods spaced apart by  
predetermined time intervals;

10 means for communicating a message to the  
patient after a recording time period has been  
signalled;

data-entering means for allowing the  
patient to enter clinical data relative to the patient  
15 and related to the message; and

memory means for receiving and storing the  
entered clinical data.

2. A portable, interactive data-logger  
20 device as recited in claim 1, in which said message  
communicating means comprises a display unit for  
displaying a question to be answered by the patient.

3. A portable, interactive data-logger  
25 device as recited in claim 1, further comprising means  
for turning the data-logger device on, wherein said  
message communicating means comprises means for

communicating a message to the patient following turning on of the data-logger device.

5           4. A portable, interactive data-logger device as recited in claim 1, further comprising means for preventing the patient to enter or alter any data entered during one of said recording time periods after said recording time period has elapsed.

10           5. A portable, interactive data-logger device as recited in claim 1, wherein:

            said message communicating means comprises means for asking to the patient what intensity of pain he is feeling; and

15           said data-entering means comprises means for allowing the patient to enter the intensity of pain he is feeling.

20           6. A portable, interactive data-logger device as recited in claim 5, wherein said means for allowing the patient to enter the intensity of pain he is feeling comprises:

            - a bar graph;  
            - pain intensity scale means along said  
25           bar graph; and  
            - pushbutton means for controlling said bar graph.

7. A portable, interactive data-logger device as recited in claim 1, wherein:

5       said message communicating means comprises means for asking to the patient what degree of discomfort he is feeling; and

      said data-entering means comprises means for allowing the patient to enter the degree of discomfort he is feeling.

10       8. A portable, interactive data-logger device as recited in claim 7, wherein said means for allowing the patient to enter the degree of discomfort he is feeling comprises:

15       - a bar graph;  
      - discomfort degree scale means along said bar graph; and  
      - pushbutton means for controlling said bar graph.

20       9. A portable, interactive data-logger device as recited in claim 1, wherein:

25       said message communicating means comprises means for asking to the patient how severe is a given symptom; and

      said data-entering means comprises means for allowing the patient to enter the severeness of said given symptom.

10. A portable, interactive data-logger device as recited in claim 9, wherein said means for allowing the patient to enter the severeness of said given symptom comprises:

- 5                   - a bar graph;
- symptom severeness scale means along said bar graph; and
- pushbutton means for controlling said bar graph.

10

11. A portable, interactive data-logger device as recited in claim 1, wherein:

- said message communicating means comprises means for asking to the patient both what intensity of pain and what degree of discomfort he is feeling; and
- 15                   said data-entering means comprises means for allowing the patient to enter both the intensity of pain and the degree of discomfort he is feeling.

20

12. A portable, interactive data-logger device as recited in claim 11, wherein said means for allowing the patient to enter the intensity of pain and the degree of discomfort he is feeling comprises:

- a first bar graph;
- 25                   - pain intensity scale means along said first bar graph;
- first pushbutton means for controlling said first bar graph;

- a second bar graph;
- discomfort degree scale means along said second bar graph; and
- second pushbutton means for controlling said second bar graph.

5

13. A portable, interactive data-logger device as recited in claim 1, comprising means for programming the time intervals between the successive recording time periods.

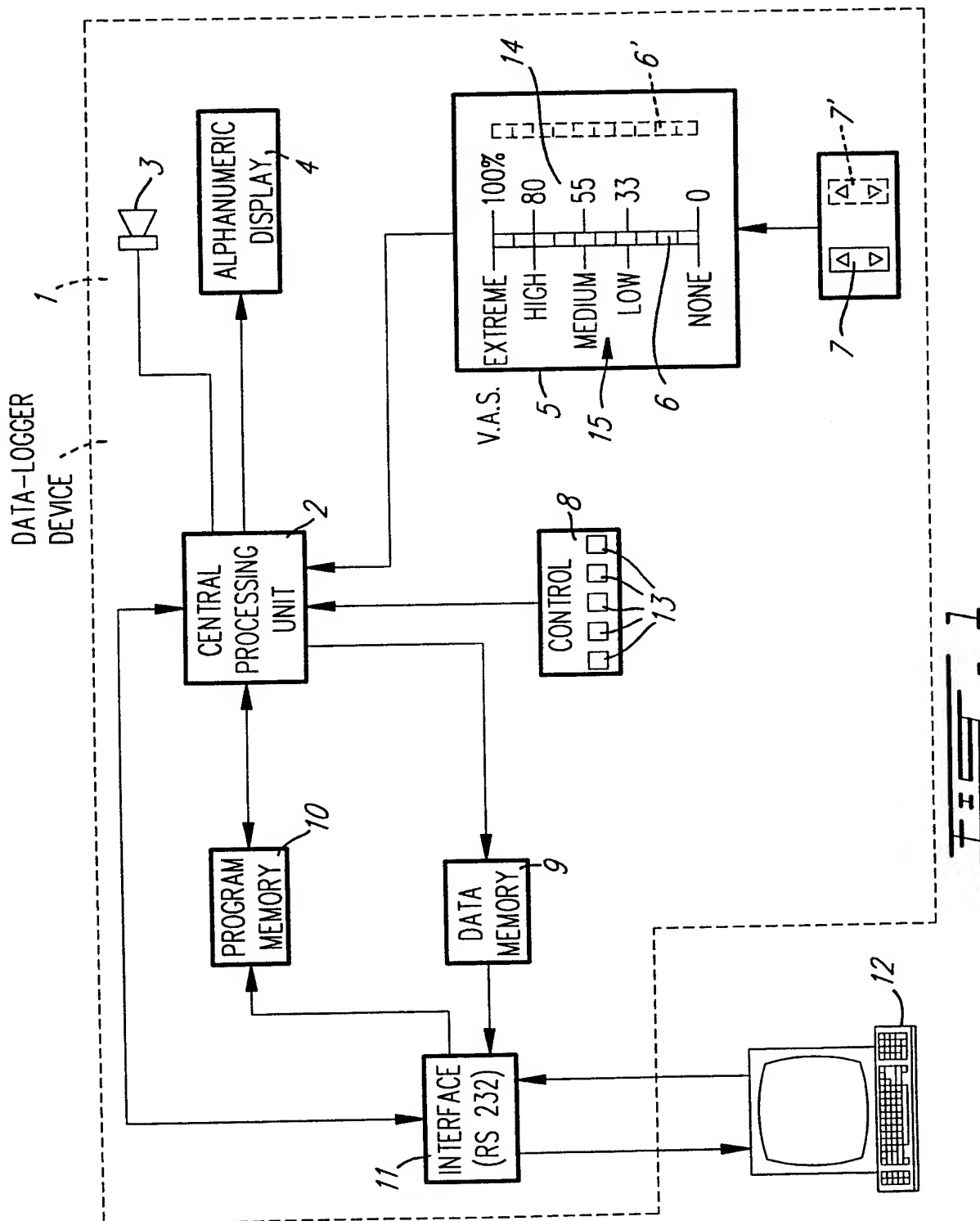
10

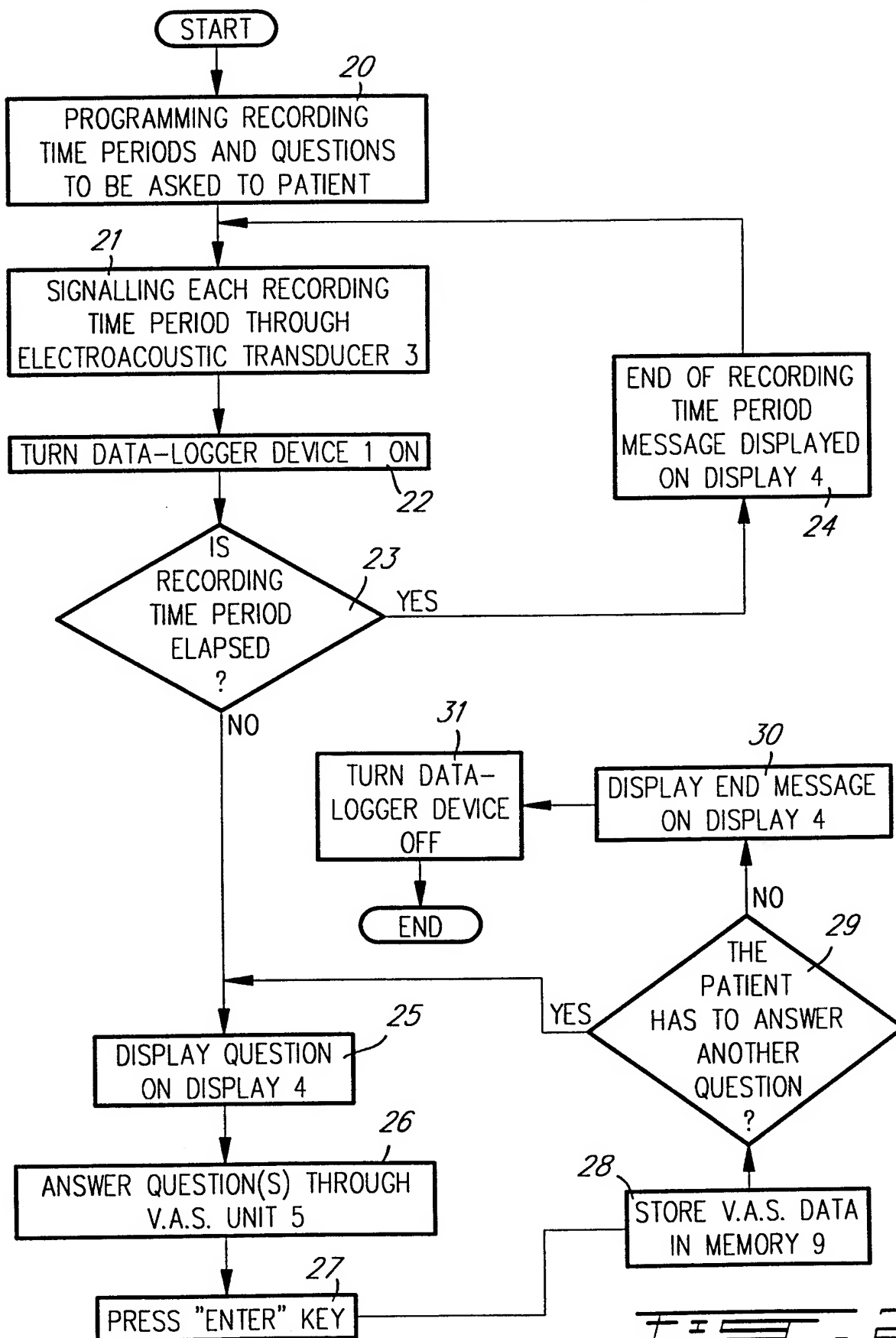
14. A portable, interactive data-logger device as recited in claim 1, comprising means for programming the message to be communicated to the patient after a recording time period has been signalled.

15

15. A portable, interactive data-logger device as recited in claim 1, wherein said message communicating means comprises means for communicating to the patient a plurality of messages, and wherein said data-entering means comprises means for allowing the patient to enter clinical data related to each of said messages.

20





## INTERNATIONAL SEARCH REPORT

International Application No

PCT/CA 97/00544

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 96 29007 A (WALKER DAVID JOHN) 26 September 1996	1
A	see page 10, line 12 - page 11, line 16	5-8,10,13,14
	see page 13, line 11 - page 18, line 7	
	see page 21, line 18 - page 22, line 15;	
	tables 1-3,11	
	---	
Y	EP 0 212 278 A (CARDIAC MONITORING SERV INC) 4 March 1987	1
A	see page 9, line 4 - page 34, line 16;	2,3,15
	table 1	
	---	
A	FR 2 727 850 A (ELA MEDICAL SA) 14 June 1996	1,3,15
	see abstract	
	see page 5, line 16 - page 9, line 24;	
	table 1	
	---	
	-/-	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&amp;" document member of the same patent family

Date of the actual completion of the international search

23 February 1998

Date of mailing of the international search report

12.03.98

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Weihs, J



# INTERNATIONAL SEARCH REPORT

International Application No

PCT/CA 97/00544

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US 5 577 510 A (CHITTUM WILLIAM R ET AL)  26 November 1996  see column 4, line 32 - column 5, line 62;  tables 1-3  -----</p>	1,15

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern. Patent Application No

PCT/CA 97/00544

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9629007 A	26-09-96	AU 5010896 A GB 2313672 A	08-10-96 03-12-97
EP 0212278 A	04-03-87	US 5012411 A AU 617862 B AU 4113189 A AU 587049 B AU 6047686 A CA 1287880 A	30-04-91 05-12-91 14-12-89 03-08-89 29-01-87 20-08-91
FR 2727850 A	14-06-96	NONE	
US 5577510 A	26-11-96	NONE	